JAN 1 2 2004

K031147

Optical DVS (Dual Vector Shearing) Esophageal Dilator 510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Kimberly Shoemaker
Senior Regulatory Affairs Associate

Date Prepared:
April 8, 2003

Name of Device
Trade Name: Optical DVS (Dual Vector Shearing) Esophageal Dilator
Classification Name: Esophageal Dilator

Predicate Devices:
Savary-Gilliard Dilators cleared under K851955 on 07/25/85

Device Description
The Optical DVS is a sterile, single use, disposable esophageal dilator for use with an endoscope to dilate esophageal strictures under endoscopic visualization. The Optical DVS is made from a clear flexible polymer. An endoscope having an outer diameter of 10mm or less, such as a standard gastroscope, is positioned within the Optical DVS to allow for visualization at the stricture site.

Indications for Use
The Optical DVS is indicated for dilation of strictures of the esophagus under endoscopic visualization.

Technological Characteristics
The Optical DVS is similar to the predicate device with respect to design. The Optical DVS allows for visualization of strictures with the use of an endoscope where as the predicate device does not.

Performance Data
Bench testing was performed to verify dilation performance. These data, combined with descriptive intended use and design information, indicate the Optical DVS is substantially equivalent to the Savary-Gilliard Dilator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 2 2004

Ms. Kimberly Shoemaker
Sr. Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
A Johnson & Johnson Co.
4545 Creek Road
CINCINNATI OH 45242-2839

Re: K031147
Trade/Device Name: OPTICAL DVS (Dual Vector Shearing) Esophageal Dilator
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: 78 KNQ
Dated: October 13, 2003
Received: October 14, 2003

Dear Ms. Shoemaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031147

Device Name: OPTICAL DVS (Dual Vector Shearing) Esophageal Dilator

Indications for Use:

The Optical DVS (Dual Vector Shearing) Esophageal Dilator is indicated for dilation of strictures of the esophagus under endoscopic visualization.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031147

Prescription Use ✓
(Per 21 CFR 801.109)